DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Food and Drug Administration
College Park, MD 20740

Colin G. Meyer, D.V.M., Ph.D.
Director, Food Analysis and Diagnostic Laboratory
2472 Schofield Road, Building 2632
Fort Sam Houston, TX 78234-6232

Re: Docket No. 02P-0013/CP 1

Dear Dr. Meyer:

This letter responds to your citizen petition dated December 3, 2001, as amended December 18, 2001, and January 10, 2003, in which you requested that the Food and Drug Administration (FDA) "rescind the Generally Recognized As Safe (GRAS) status for aluminum-containing food additives," specifically sodium aluminum sulfates, sodium aluminum phosphates, and aluminum sulfates (collectively referred to as aluminum salts), due to epidemiological studies linking dietary aluminum with risk of Alzheimer's disease (AD). You acknowledge that the information you presented "is not intended to establish proof that aluminum exposure is the cause of AD. The etiology of this disease remains unknown." Further, you state that "the potential for aluminum-containing food additives to be causal or contributory factors for AD clearly deserves further examination."

In accordance with Title 21 of the Code of Federal Regulations (21 CFR) section 10.30(e)(3), this letter is to advise you that FDA is denying your petition without prejudice to your resubmission of a new petition with supporting data submitted in accordance with the requirements prescribed in 21 CFR 10.30(b) and 10.20(c) that demonstrates there is a link between dietary aluminum and risk of AD.

You did not provide complete copies of the references which you relied on to support your petition. Specifically, you did not provide full copies of references 1 through 11 which you cited in your original submission, and you provided only abstracts of three papers and only the first page from each of five published papers. In letters dated January 27, 2003, and August 13, 2003, FDA offered you the opportunity to make your petition whole by requesting you to submit full copies of all references that were used to support your petition in accordance with 21 CFR 10.30(b) and 10.20(c). You did not respond to our request for complete copies of the references.

Under 21 CFR 10.20(c), "[i]nformation referred to or relied upon in a submission is to be included in full and may not be incorporated by reference, ..." Furthermore, "[t]he failure to comply with the requirements of this part ... will result in rejection of the submission for filing or, if it is filed, in exclusion from consideration of any portion that fails to comply." 21 CFR 10.20(c)(6). Thus, the citations to references that you have not supplied have not been considered.

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You provided full copies of four published papers that describe epidemiological studies pointing to a possible association between aluminum intake and AD. However, you did not explain how these studies relate to the GRAS status of aluminum-containing food ingredients.

FDA cannot take the actions you requested without a clear basis for supporting a conclusion that the current use of aluminum salts in food is not considered GRAS by qualified experts. For the reasons discussed above, your petition does not provide that support. Therefore, FDA is denying your petition.

We appreciate your interest in this issue. For your information, we have included a copy of a proposed rule that addressed the issues you raised concerning the link between aluminum-containing food ingredients and AD (60 FR 57132; November 13, 1995; copy enclosed).

Sincerely yours,

John M. Taylor, III
Associate Commissioner
for Regulatory Affairs

Enclosure